

(English) C-TEK® ANTERIOR CERVICAL PLATE SYSTEM

INDICATIONS FOR USE

The Biomet **C-Tek** Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in the temporary stabilization of the anterior spine from C2 to C7 during the development of cervical spinal fusions in patients with: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures); primary and metastatic malignant tumors; deformity (defined as kyphosis, lordosis, or scoliosis); pseudarthrosis; failed previous fusions; and/or spinal cord stenosis and cervical myelopathy.

DESCRIPTION OF DEVICE

The **C-Tek** Anterior Cervical Plate System components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The **C-Tek** Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates, screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

NOTE: This device system is intended for anterior cervical intervertebral body fusion only.

PRODUCT CONFIGURATIONS

The **C-Tek** Anterior Cervical Plate System implants are provided nonsterile and should be cleaned and sterilized prior to use. The **C-Tek** Anterior Cervical Plate System implants are made from surgical implant grade titanium alloy as described by ASTM Standard F-136 (Ti 6Al-4V ELI).

INSTRUCTIONS FOR USE

Caution: The **C-Tek** Anterior Cervical Plate System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to the **C-Tek** Anterior Cervical Plate System Instrumentation Technique Manual for complete Instructions For Use.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, local to the operative site;
2. morbid obesity;
3. mental illness;
4. signs of local inflammation;
5. fever or leukocytosis;
6. pregnancy;
7. metal sensitivity/allergies to the implant materials;
8. any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
9. grossly distorted anatomy due to congenital abnormalities;
10. rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft);
11. any case not needing a bone graft and fusion or where fracture healing is not required;
12. any case requiring the mixing of metals from different components;
13. any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition;
14. any case not described in the Indications;
15. any patient unwilling to cooperate with the postoperative instructions;
16. any time implant utilization would interfere with anatomical structures or expected physiological performance.

WARNINGS

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct. The **C-Tek** Anterior Cervical Plate System should not be used with the components from any other system or manufacturer. As with all orthopaedic implants, the **C-Tek** Anterior Cervical Plate System should never be reused under any circumstances.
2. This device system is not intended to be the sole means of support. Its use without a bone graft or in cases that develop into a nonunion will not be successful. No implant can withstand the loads of the body without maturation of a solid fusion mass. If there is no solid fusion, the implant will eventually bend, loosen, or fracture.
3. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
4. Always orient the **C-Tek** Anterior Cervical Plate as close as possible along the midline of the spine.
5. The Step Drills are for single intraoperative use only and are not to be reused.
6. Repeated opening and closing of the cover plate may compromise the integrity of the locking mechanism.

PRECAUTIONS

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The **C-Tek** Anterior Cervical Plate System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
7. Carefully inspect all instruments prior to use. Do not use an instrument that is severely marred and/or worn, or a cutting instrument with dull edges. Note that at some point in time, instruments may wear out and should be replaced.

Intraoperative:

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
4. The implant surfaces should not be scratched or notched since such actions may reduce the functional strength of the construct.

5. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
7. Extreme caution should be used around the spinal cord and nerve roots, especially when inserting screws. Breakage, slippage, misuse, or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel.
8. Prior to closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Also, secure the cover plate to block the screw heads. Failure to do so may result in screw loosening.

CAUTION: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
4. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
5. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
6. The **C-Tek** Anterior Cervical Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: a) corrosion, with localized tissue reaction or pain, b) migration of implant position possibly resulting in injury, c) risk of additional injury from postoperative trauma, d) bending, loosening and/or breakage, which could make removal impractical or difficult, e) pain, discomfort, or abnormal sensations due to the presence of the device, f) possible increased risk of infection, and g) bone loss due to stress shielding. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to heal is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a

second surgical procedure and the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.

7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the **C-Tek** Anterior Cervical Plate System components should ever be reused under any circumstance.

COMPLICATIONS

Possible adverse effects include, but are not limited to:

1. bending, loosening or fracture of the implants or instruments
2. sensitivity to a metallic foreign body, including possible tumor formation
3. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications
4. nonunion or delayed union
5. infection
6. nerve or vascular damage due to surgical trauma, including loss of neurological function such as paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation
7. dural tears
8. neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis
9. loss of bowel and/or bladder control or other types of urological system compromise
10. fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery
11. interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants
12. gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium
13. bone loss due to resorption or stress shielding
14. hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels
15. malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
16. change in mental status
17. bone graft donor site complications including pain, fracture, or wound healing problems
18. atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft
19. inability to resume activities of normal daily living
20. cessation of any potential growth of the operated portion of the spine
21. loss of spinal mobility or function
22. reoperation
23. death.

STERILIZATION

All **C-Tek** Anterior Cervical Plate System components are provided nonsterile. All packaging should be sealed and intact upon receipt. If the package or product is damaged, it should not be used and should be returned immediately.

High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following cycle has been laboratory validated:

Method:	Steam
Cycle:	Pre-vacuum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes

NOTE: Allow for Cooling

CAUTION

Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.

INFORMATION

For further information, please contact the Customer Service Department at:

Biomet
100 Interpace Parkway
Parsippany, NJ 07054
(973) 299-9300
800-526-2579
www.biometspine.com

U.S. Patent Numbers: 6,224,602; 6,602,256



Authorized European Representative
Biomet UK Ltd.
Waterton Industrial Estate
Bridgend
CF31 3XA UK



100 Interpace Parkway
Parsippany, NJ 07054
www.biometspine.com
800-526-2579
973-299-9300

7078 Copyright ©2008. EBI, LLC. All rights reserved.

All trademarks are the property of Biomet, Inc. or one of its subsidiaries, unless otherwise indicated.

P/N 01-50-3116 2/09